

### DETAILED ACTION

1. Amendment and response filed by applicants dated Apr. 27, 2011 have been entered and considered carefully.

Claims 1-15, 17, 32-27 have been canceled. Claims 16, 18-31 and 38-44 are pending.

Claims 16, 18-31 are continuously prosecuted. Claims 38-44 stayed withdrawn from consideration per 37 CFR 1.142(b).

2. The amendment of incorporating claim 17 into the base claim thus limiting the compounds being  $n=2$  and the deletion of "solvates" have obviated the rejection of claims 16, 18-22, 23-24, 29 under 35 USC 112 first paragraph.

It is incorrect to argue that claims 38-44 are species fell within the genus. Please note that specific crystalline form of a compound does not fall within the scope of claim 1. As it was explained and conventionally recognized in the art that polymorphic crystalline forms of a specific compound especially a hydrate of a salt of formula I is "not" the same chemical identity as the compound per se (see previously cited Seddon) or its prima facie acid addition salt with pharmaceutically acceptable acids. Therefore, polymorphic crystalline forms of hydrates/salts are patentably distinct invention since polymorphic forms of a known compound is patentable, and requires separate examination. Process of making crystalline solvates/hydrates of salts or compounds are considered a nightmare when in possession of the compound per se (see previously cited Braga p.3640). Therefore, the restriction is proper and is hereby made final.

3. This application is in condition for allowance except for the following formal matters:

The cancellation of the non-elected claims 38-44.

Prosecution on the merits is closed in accordance with the practice under *Ex parte Quayle*, 25 USPQ 74, 453 O.G. 213, (Comm'r Pat. 1935).

A shortened statutory period for reply to this action is set to expire **TWO MONTHS** from the mailing date of this letter.

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4. Claims 16, 18-31 are objected to because applicants argued that the base claims included solvates which term has been deleted. Were the claims limited to no solvates which would be different from claims 38-44, the claims are allowable after cancellation of claims 38-44.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*OACS/Chang*  
*Kul. 7, 2011*

*/Celia Chang/*  
*Primary Examiner*  
*Art Unit 1625*